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T-D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/180,335	02/25/99	COOKSON	A P/222-45

IM22/1219
OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK NY 10036-8403

EXAMINER

SNAY, J

ART UNIT	PAPER NUMBER
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1743

DATE MAILED:

12/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application N .

09/180,335

Applicant(s)

COOKSON ET AL.

Examiner

Jeffrey R. Snay

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 20) ☐ Other: _____

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1. Applicant's election with traverse of claims 1-7 in Paper No. 7 is acknowledged. The traversal is on the ground(s) that claim 7 in group I repeats a special technical feature that is found in claim 8 of Group II. Applicant further asserts that the device recited in claim 9 of group II is the same as that recited in the kit of Group III. This is not found persuasive because the holding of lack of unity is based upon independent claims. The elected group is represented by independent claim 1 and applicant has offered no reasoning in support of a special technical feature recited in claim 1 with the independent claims of either group II or group III.

The requirement is still deemed proper and is therefore made FINAL.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 12 and 13 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tosa et al (EP 0667528).

Tosa et al disclose a method for analyte detection comprising contacting a sample with an optical waveguide, having an antibody coated thereon, and determining an analyte from a continuously measured fluorescence emission. See particularly Figures 2 and 3 and associated description thereof.

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4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 6, 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tosa et al (EP 0667528) in view of Sutherland et al (EP 0184600).

The pertinent portion of Tosa et al is described above. The method of Tosa et al differs from the presently claimed invention in that it fails to specify the waveguide as forming a capillary fill device, and further fails to set out the claimed steps of calibration. Regarding the former, Sutherland et al teach a capillary filled waveguide for accurately contacting a fixed sample volume continuously to an antibody coated surface of a waveguide. It would have been obvious to one of ordinary skill in the art to construct the waveguide of Tosa et al in the manner taught by Sutherland et al in order to obtain the known advantages thereof, including continuous flow through analysis of a sample and controlled contact between a sample solution and the waveguide surface. As to the

latter, see Sutherland et al at page 25 describing the well known and conventional steps of analyzing a plurality of samples of known analyte concentration for calibration purposes. It would have been obvious to the skilled artisan to perform such a calibration in the method of Tosa et al as such would have been inherently required, and was notoriously well known, for calibration of the measurement device prior to analysis of a sample of unknown analyte concentration.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as general background information related to continuous monitoring of an optical waveguide for analyte detection.

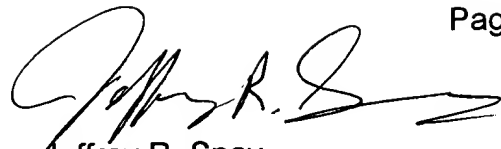
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (703) 308-4032. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7718 for regular communications and (703) 308-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 306-5665.

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A handwritten signature in black ink, appearing to read "Jeffrey R. Snay". The signature is fluid and cursive, with a long horizontal stroke at the end.

Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs
December 14, 2000